#2389

THE IMPACT OF NEI-FUNDED MULTI-CENTER TRIALS
BIBLIOMETRIC INDICATIONS OF DISSEMINATION, ACCEPTANCE AND IMPLEMENTATION OF TRIAL FINDINGS

PAMELA C. SIEVING* National Institutes Of Health Library, Bethesda USA

STUDY DESIGN

PURPOSE:

Use bibliometric techniques to examine the impact of 5 NEI-funded multi-center clinical trials.

METHODS:

1) Identify trial findings & recommendations for interventions from 5 trials:
   - Vision screening for preschool children (**VIP**)
   - Patching for amblyopia (**PEDIG**)
   - Nutritional supplements for age-related macular degeneration (**AREDS**)
   - Medical vs surgical interventions for open-angle glaucoma (**CIGTS**)
   - Radiation vs enucleation for choroidal melanoma (**COMS**)

2)Track dissemination of trial results by:
   - Indexing in bibliographic databases,
   - Citation analyses,
   - Inclusion in the Cochrane Library and in Cochrane systematic reviews,
   - Inclusion of trial reports in institutional repositories indexed by www.oaister.org
   - Popular access points such as Google and newspapers.

3) Track acceptance and implementation of recommendations and primary findings by:
   - References in guidelines, standards of care, expert panel recommendations,
   - Inclusion in the two current monographs which summarize the evidence base for ophthalmic practice,
   - Economic analyses of the study's impact.

4) Examine the availability of trial reports in open access sources.

RESULTS:

1) Science Citation Index (Web of Knowledge), SCOPUS and Google Scholar track citations. The first two provide unique but overlapping access to the journal literature. Google Scholar (scholar.google.com) retrieves dissertation, monograph, and grey literature content in addition to some journal literature unidentified by Medline, Embase, etc.

2) Reports of a well-known trial such as AREDS I may be cited more than 100 times in the first year after publication or as few as 15 times within 5 years of publication.

3) Trial reports can be difficult to identify. Group authorship standards are inconsistent over the life of many trials; the status of a publicaion as an official trial report may be noted only in a footnote.

4) Systematic reviews are more likely than guidelines, consensus statements, and 'reviews of the literature' to identify and discuss all relevant trial findings.

5) Few economic-impact analyses were identified for these trials.

6) None of the trial reports are available on indexed institutional repositories.

6) Free access to NIH-funded research is inconsistent despite the availability of the PubMed Central archive and institutional repositories available for individuals, institutions, and trial groups.

CONCLUSIONS:

1) Evaluations of the impact of a trial's findings and recommendations should include
   -- searches of multiple bibliographic databases
   -- Web searches
   -- searches within Web- and print-based resources of relevant organizations.

2) Inconsistent and incomplete authorship listings across multiple papers makes it difficult to retrieve the information.

3) Evidence-based guidelines and standards of care should the document sources that were used to establish "strength of evidence" ratings.

4) The benefits of these studies can be maximized by:
   -- Increasing the access to trial results using open access publication,
   -- Depositing the information in pre- and post-print repositories,
   -- Increasing the opportunities for free or inexpensive access to study results by ARVO, the two vision academies, research funders, and other organizations.

FINDINGS

AREDS I: 20 reports, 1999-2006


National Eye Institute NIH

Report #8, recommending antioxidant + zinc supplements (Arch Ophthalmol 2001; 119:1417) cited >400x
AAO Preferred Practice Pattern (2005) cites & references AREDS
ICO International Clinical Guidelines (2007) include but do not reference AREDS
RCO AMD Interim Guidelines (2005) include & reference AREDS
Cochrane Collaboration systematic review (2005) includes & references AREDS
Cochrane Library indexes economic impact of AREDS vs Visudyne (Ophthalmic Epidemiol 2004; 11:337)
Wormald (2004) discusses AREDS, but Kertes & Johnson (2007) do not
All reports are available free fulltext in **PubMed Central**

CIGTS: 7 reports, 1999- 2006

2001 report (Ophthalmology 108:1943) noting similar medical & surgical outcomes cited >200x
AAO Preferred Practice Pattern (2005) cites & references CIGTS findings
ICO guidelines for primary open-angle glaucoma do not reference CIGTS
RCO Guidelines for the Management of Open Angle Glaucoma and Ocular Hypertension (2004) incorporate but do not reference CIGTS findings
Finnish evidence-based guideline cites & references CIGTS findings (Acta Ophthalmol Scand 2003: 81:31)
Cochrane Collaboration systematic review (2004) includes CIGTS
Cochrane Library includes several economic evaluations incorporating CIGTS findings (Acta Ophthalmol Scand 2006; 84:74; Can J Ophthalmol 2006; 41:449)
AHRQ links to Singapore Ministry of Health guidelines (2004) citing CIGTS
Both Wormald and Kertes & Johnson include CIGTS in their discussions of evidence-based glaucoma practice
One report (Invest Ophthalmol Vis Sci 2003; 44:2613) is available free fulltext

COMS: 28 reports, 1990-2006

2001 report #18 of initial mortality findings (Arch Ophthalmol 119:1067) cited >110x
No AAO, ICO or RCO guidelines for this intervention
No Cochrane systematic review on choroidal melanoma
Cochrane Library includes COMS reports in Central register of clinical trials
Wormald and Kertes & Johnson both include COMS in their reviews
No COMS reports are currently available free fulltext


National Eye Institute NIH

PEDIG: Patching Studies - 17 reports, 2001-2007

2002 report comparing atropine & patching (Arch Ophthalmol 120:268) cited >100x
AAO Preferred Practice Pattern on amblyopia (2002) includes the PEDIG finding comparing atropine & patching
A 2002 cost-utility analysis of amblyopia (Ophthalmology 109:2265) finds amblyopia therapy cost-effective compared to other health care interventions
ICO guideline on Amblyopia (2007) incorporates but does not reference PEDIG findings
No Cochrane systematic review on this topic has been completed since the PEDIG study was published
AHRQ indexes guidelines from the American Academy of Optometry in 2004 which do not refer to the PEDIG findings; USPSTF guidelines on screening for visual impairment in children younger than 5 years (updated in 2004) include PEDIG findings,
Wormald does not include PEDIG studies, but the Kertes & Johnson chapter on amblyopia, authored by PEDIG investigators, does.
One PEDIG paper is available free fulltext.

VIP: Vision Screening Studies - 13 reports, 1998-2007

2004 report comparing several screening tests administered by licensed eye care professionals (Ophthalmology 111:637) cited >50x
AAO Preferred Practice Pattern on Pediatric Eye Evaluations was produced before this report.
AAO policy statement on eye examinations of children, issued jointly with the American Association of Certified Orthoptists, American Association for Pediatric Ophthalmology & Strabismus, and the American Academy of Pediatrics (Pediatrics 2003; 111:902) does not reference VIP studies.
Cochrane systematic review on screening for amblyopia (2005) includes discussion of VIP studies; the 2004 review on vision screening for correctable visual acuity deficits in school-age children and adolescents does not.
The American Academy of Pediatrics guideline on the use of photoscreening (Pediatrics 2002; 109:524), and on eye exams for infants, children and young adults (Pediatrics 2003; 111:902) do not reference VIP studies.
Neither Wormald nor Kertes & Johnson discuss screening studies.
One VIP paper is available free fulltext.

MEASURES OF TRIAL DISSEMINATION

Database Calculations:
based on citations in documents indexed by the database

Web of Knowledge:

All AREDS papers

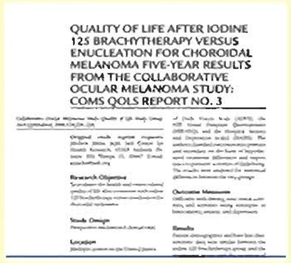
AREDS reports published in 2001

SCOPUS

Two AREDS reports published in 2001

Trial Coverage by Professional and Popular Press

Evidence-Based Ophthalmology 2006; 7:154


QUALITY OF LIFE AFTER IODINE 125 BRACHYTHERAPY VERSUS ENUCLEATION FOR CHOROIDAL MELANOMA FIVE-YEAR RESULTS FROM THE COLLABORATIVE OCULAR MELANOMA STUDY: COMS QOLS REPORT NO. 3

New York Times


VITAL SIGNS: UPDATE; An Easier Aid for a Lazy Eye

References:

American Academy of Ophthalmology Preferred Practice Patterns:
www.aao.org/education/guidelines/ppp/index.cfm
International Council of Ophthalmology International Clinical Guidelines:
www.icoph.org/guide/
The Royal College of Ophthalmologists publications:
www.rcophth.ac.uk/scientific/publications
Kertes PJ, Johnson TM. Evidence-Based Eye Care. LWW, 2007.
Wormald R, Smeeth L, Henshaw K. Evidence-Based Ophthalmology. BMJ , 2004.

*The author has no commercial interest in any product or service mentioned in this study